

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Dakai Liu and Elazar Rabbani )  
Serial No. 08/822,963 )  
Filed: March 21, 1997 )  
Title: VECTORS, VIRAL VECTORS AND )  
PACKAGING CELL LINES FOR )  
PROPAGATING SAME )

Group Art Unit: 1631

Examiner: David Guzo

527 Madison Avenue, 9<sup>th</sup> Floor  
New York, New York 10022  
January 11, 2002

**FILED VIA EXPRESS MAIL**

Honorable Commissioner of Patents and Trademarks  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§1.56 & 1.97-1.98**

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following forty-nine (49) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

Enz-56

Dakai Liu and Elazar Raubani

Serial No.: 08/822,963

Filed: March 21, 1997

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-- January 11, 2002]

**EXPRESS MAIL CERTIFICATE**

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I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

MCE  
Ronald C. Fedus

JAN 11 2002  
Date

Reg. Exhibit 32,567

Enz-5(D8)(C2)

Dakai Liu and Elazar Rubani

Serial No.: 08/822,963

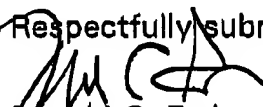
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The fee under 37 C.F.R. §1.17(p) for filing this Supplemental Information Disclosure Statement is \$180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



Ronald C. Fedus

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\* \* \* \* \*

Footnotes

<sup>1</sup>Cited in the specification of the instant application, serial no. 08/822,963 filed 03/21/97.

<sup>2</sup>Cited by the Examiner on form PTO 892 in connection with an Office Action issued 06/05/98 in connection with the instant application, serial no. 08/822,963, filed 03/21/97.

<sup>3</sup>Cited in an Amendment under 37 C.F.R. §1.115 (in response to June 5, 1998 Office Action) in connection with the instant application, serial no. 08/822,963 filed 03/21/97.

<sup>4</sup>Cited in an Office Action issued 08/25/99 in connection with the instant application, serial no. 08/822,963 filed 03/21/97.

<sup>5</sup>Cited in an Amendment Under 37 C.F.R. §1.116 (in response to August 25, 1999 Office Action) in connection with the instant application, serial no. 08/822,963, filed 03/21/97.

<sup>6</sup> This document is not presently available.

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Enz-5(D8)(C2)

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2. Anderson, W.F, "Human Gene Therapy," Science 256:808-813 (1992) [EXHIBIT 2]<sup>1</sup>
3. Mulligan, R.C, "The Basic Science of Gene Therapy," Science 260:926-932 (1993) [EXHIBIT 3]<sup>1</sup>
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5. Muzyczka, N, "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," Current Topics in Microbiology and Immunology 158:97-129 (1992) [EXHIBIT 5]<sup>1</sup>
6. Kotin, R.M, "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy," Human Gene Therapy 5:793-801 (1994) [EXHIBIT 6]<sup>1</sup>
7. Berliner, K.L, Curr. Top. Microbiol. Immunol. 158:39-66 (1992)[EXHIBIT 7]<sup>1,6</sup>
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9. Emerman, M et al., "Quantitative Analysis of Gene Suppression in Integrated Retrovirus Vectors," Molecular and Cellular Biology 6(1):792-800 (1986) [EXHIBIT 9]<sup>1</sup>
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11. Yu, S.F et al., "Self-inactivating retroviral vectors designed for transfer of whole genes into mammalian cells," Proc. Natl. Acad. Sci. USA 83:3194-3198 (1986) [EXHIBIT 11]<sup>1</sup>
12. Hawley, R.G. et al., "Handicapped retroviral vectors efficiently transduce foreign genes into hematopoietic stem cells," Proc. Natl. Acad. Sci. USA 84: 2406-2410 (1987) [EXHIBIT 12]<sup>1</sup>

13. Yee, J.K et al., "Gene expression from transcriptionally disabled retroviral vectors," Proc. Natl. Acad. Sci. USA 84:5197-5201 (1987) [EXHIBIT 13]<sup>1</sup>
14. Dougherty, J.P and Temin H.M., "A promoterless retroviral vector indicates that there are sequences in U3 required for 3' RNA processing," Proc. Natl. Acad. Sci. USA 84:1197-1201 (1987) [EXHIBIT 14]<sup>1,2,3</sup>
15. Whitcomb, J.M and Hughes, S.H., "Retroviral Reverse Transcription and integration: Progress and Problems" Ann. Rev. Cell Biol. 8:275-306 (1992) [EXHIBIT 15]<sup>1</sup>
16. Jaenisch, R et al., "Germline Integration of Moloney Murine Leukemia Virus at the Mov13 Locus Leads to Recessive Lethal Mutation and Early Embryonic Death," Cell 32:209-216 (1983) [EXHIBIT 16]<sup>1</sup>
17. Fung, Y.T. et al., "On the mechanism of retrovirus-induced avian lymphoid leucosis: Deletion and integration of the proviruses," Proc. Natl. Acad. Sci. USA 78(6):3418-3422 (1981) [EXHIBIT 17]<sup>1</sup>
18. Neel, B.G. and Hayward W.S., "Avian Leukosis Virus-Induced Tumors Have Common Proviral Integration Sites and Synthesize Discrete New RNAs: Oncogenesis by Promoter Insertion," Cell 23:323-334 (1981) [EXHIBIT 18]<sup>1</sup>
19. Payne, G.S. et al., "Analysis of Avian Leukosis Virus DNA and RNA in Bursal Tumors: Viral Gene Expression is Not Required for Maintenance of the Tumor State," Cell 23:311-322 (1983) [EXHIBIT 19]<sup>1</sup>
20. Lewin, B. Genes V; Oxford University Press, New York (1994) [EXHIBIT 20]<sup>1,8</sup>
21. Samulski, R.J et al., "Targeted integration of adeno-associated virus (AAV) into human chromosome 19," The EMBO Journal 10(12):3941-3950 (1991) [EXHIBIT 21]<sup>1</sup>
22. Kotin, R.M et al., "Mapping and Direct Visualization of a Region-Specific Viral DNA Integration Site on Chromosome 19q13-qter," Genomics 10:831-834 (1991) [EXHIBIT 22]<sup>1</sup>
23. Kotin et al., "Site-specific integration by adeno-associated virus," Proc. Natl. Acad. Sci. USA 87:2211-2215 (1990) [EXHIBIT 23]<sup>1</sup>
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Spring Laboratory, Cold Spring Harbor, NY, 1989 [EXHIBIT 24]<sup>1,6</sup>

25. Manser, T. and Gesteland R.F., "Human U1 Loci: Genes for Human U1 RNA Have Dramatically Similar Genomic Environments." Cell 29:257-264 (1982) [EXHIBIT 25]<sup>1</sup>
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27. Wells S. et al., "The presence of an autologous marrow stromal cell layer increases glucocerebrosidase gene transduction of long-term culture initiating cells (LTCICs) from the bone marrow of a patient with Gaucher disease," Gene Therapy 2:512-520 (1995) [EXHIBIT 27]<sup>1</sup>
28. Bertolini F. et al., "Engineered Stromal Layers and Continuous Flow Culture Enhance Multidrug Resistance Gene Transfer in Hematopoietic Progenitors," Cancer Research 56:2566-2572 (1996) [EXHIBIT 28]<sup>1</sup>
29. Xu L.C. et al., "Growth Factors and Stromal Support Generate Very Efficient Retroviral Transduction of Peripheral Blood CD34<sup>+</sup> Cells From Gaucher Patients." Blood, 86(1):141-146 (1995) [EXHIBIT 29]<sup>1</sup>
30. Nolte J.A. et al., "Analysis of Optimal Conditions for Retroviral-Mediated Transduction of Primitive Human Hematopoietic Cells," Blood 86(1):101-110 (1995) [EXHIBIT 30]<sup>1</sup>
31. Rabbani E. et al., U.S. Patent Application Serial No 08/574,443 filed on December 15, 1995, abandoned in favor of U.S. Patent Application Serial No. 08/978,632 filed 11/25/97 [EXHIBIT 31]<sup>1</sup>
32. Maddon, P.J et al., Cell 47:333-348 (1986) [EXHIBIT 32]<sup>1,6</sup>
33. Lever, A.M.L, "Gene therapy for HIV infection," British Medical Bulletin, 51(1):149-166 (1995) [EXHIBIT 33]<sup>1</sup>
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35. Wagner E. et al., "Coupling of adenovirus to transferring-polysine/DNA complexes greatly enhances receptor-mediated gene delivery and expression

of transfected genes." Proc. Natl. Acad. Sci. USA 89: 6099-6103 (1992) [EXHIBIT 35]<sup>1</sup>

36. Wu et al., U.S. Patent No. 5,166,320 [EXHIBIT 36]<sup>1</sup>
37. Ruoslahti E. et al., "Alignment of Biologically Active Domains in the Fibronectin Molecule," The Journal of Biological Chemistry 256(14):7277-7281 (1981) [EXHIBIT 37]<sup>1</sup>
38. Crisitiano R.J. et al., "Hepatic gene therapy: Adenovirus enhancement of receptor-mediated gene delivery and expression in primary hepatocytes," Proc. Natl. Acad. Sci. USA 90:2122-2136 [EXHIBIT 38]<sup>1</sup>
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40. Wagner E. et al., "Influenza virus hemagglutinin HA-2 N-terminal fusogenic peptides augment gene transfer by transferring-polysine-DNA complexes: Toward a synthetic virus-like gene-transfer vehicle," Proc. Natl. Acad. Sci. USA 89:7934-7938 (1992) [EXHIBIT 40]<sup>1</sup>
41. Pergolizzi et al., U.S. Patent Application Serial No 491,929, refiled on June 7, 1995 under U.S. Patent Application Serial No. 08/479,995 [EXHIBIT 41]<sup>1</sup>
42. Zieve, G.W and Sauterer R.A., "Cell Biology of the snRNP Particles," Biochemistry and Molecular Biology 25(1):1-46 (1990) [EXHIBIT 42]<sup>1</sup>
43. Argos P. et al., "The integrase family of site-specific recombinases: regional similarities and global diversity," The EMBO Journal 5(2):433-440 (1986) [EXHIBIT 43]<sup>1</sup>
44. Sattentau, Q.J. and Weiss, R.A., "The CD4 Antigen: Physiological Ligand and HIV Receptor," Cell 52:631-633 (1988) [EXHIBIT 44]<sup>1</sup>
45. Robinson, W.S: "Hepadnaviridae and their replication in Field, BN (ed.)" Virology, 2; 2nd Ed., 2137-2169 (1989) [EXHIBIT 45]<sup>1,6</sup>
46. Craigle, R. et al., Cell 62:829-837 (1990) [EXHIBIT 46]<sup>1</sup>
47. Liu, D. et al., "Stable Human Immunodeficiency Virus Type 1 (HIV-1) Resistance in Transformed CD4<sup>+</sup> Monocytic Cells Treated with Multitargeting

Dakai Liu and Elazar Raobani

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Filed: March 21, 1997

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HIV-1 Antisense Sequences Incorporated into U1 snRNA," Journal of Virology 71(5):4079-4085 (1997) [EXHIBIT 47]<sup>1</sup>

48. Thompson et al., U.S. Patent No. 5,750,390 [EXHIBIT 48]<sup>2,3</sup>

49. Greatbach et al., U.S. Patent No. 5,324,643 [EXHIBIT 49]<sup>2,3,4,5</sup>

A completed Form PTO-1449 listing the 49 above-submitted documents is also attached hereto as Exhibit 50.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

Enz-5(D8)(C2)



Form PTO-1449 U.S. Department of Commerce (REV. 8-83) Patent and Trademark Office  <b>INFORMATION DISCLOSURE CITATION</b> (use several sheets if necessary)	Atty. Docket ENZ-56	Serial No. 08/822,963
	Applicants: Dakai Liu and Elazar Rabbani	
	Filed: March 21, 1997	Group: 1631

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE
	0	8	9	7	8	6	3	2		Rabbani et al.			
		5	1	6	6	3	2	0		Wu et al			
	0	8	4	7	9	9	9	5		Pergolizzi et al.			
		5	7	5	0	3	9	0		Thompson et al.			
		5	3	2	4	6	4	3		Greatbach et al.			

## FOREIGN PATENT DOCUMENTS

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	W O	9	8	3	7	9	1	7					

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Morgenstern, J.P. et al, "Choice and Manipulation of Retroviral Vectors," <u>Gene Transfer and Expression Protocols. Methods in Molecular Biology, Vol. 7:181-193;</u> (1991), Murray, E.J., Ed., The Humana Press, New Jersey
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	Mulligan, R.C, "The Basic Science of Gene Therapy," <u>Science 260:926-932(1993)</u>
	Smith, A.E, "Viral Vectors in Gene Therapy," <u>Ann Rev. Microbiol, 49:807-38(1995)</u>
	Muzyczka, N, "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," <u>Current Topics in Microbiology and Immunology 158:97-129</u>
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Form PTO-1449 U.S. Department of Commerce (REV. 8-83) Patent and Trademark Office  <b>INFORMATION DISCLOSURE CITATION</b> (use several sheets if necessary)	Atty. Docket # <b>ENZ-56</b>	Serial No. <b>08/822,983</b>
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	Ruoslahti E. et al., "Alignment of Biologically Active Domains in the Fibronectin Molecule," <u>The Journal of Biological Chemistry 256(14):7277-7281 (1981)</u>
	Crisitiano R.J. et al., "Hepatic gene therapy: Adenovirus enhancement of receptor-mediated gene delivery and expression in primary hepatocytes," <u>Proc Natl. Acad. Sci. USA 90:2122-2136</u>
	Curiel D.T. et al., "Adenovirus enhancement of transferring-polysine-mediated gene delivery," <u>Proc. Natl. Acad. Sci. USA 88:8850-8854 (1991)</u>
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	Sattentau, Q.J. and Weiss, R.A., "The CD4 Antigen: Physiological Ligand and HIV Receptor," Cell 52:631-633 (1988)
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	Liu, D. et al., "Stable Human Immunodeficiency Virus Type 1 (HIV-1) Resistance in Transformed CD4 <sup>+</sup> Monocytic Cells Treated with Multitargeting HIV-1 Antisense Sequences Incorporated into U1 snRNA," Journal of Virology 71(5):4079-4085 (1997)

**EXAMINER****DATE CONSIDERED**

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Dakai Liu and Elazar Rabbani

Serial No. 08/822,963

Group Art Unit: 1631

Filed: March 21, 1997

Examiner: David Guzo

Title: VECTORS, VIRAL VECTORS AND PACKAGING CELL LINES FOR PROPAGATING SAME

TRANSMITTAL  
INFORMATION DISCLOSURE STATEMENT

HON. COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

Sir:

Transmitted herewith is a Second Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. [ ] For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. [ ] For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.

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3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
- ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
  - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
  - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
- ☐ A check in the amount of \$240.00 is enclosed in payment of the fee.
  - ☒ Charge the fee to Deposit Account No. 05-1135, Order No. ENZ-56. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.
7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:

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- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
- b. the attached petition requesting consideration of this Information Disclosure Statement; and
- c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.

8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:

- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
- b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
- c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.

9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

10. ☐ A check in the amount of \$130.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

☐ Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. \_\_\_\_\_. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

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[x] The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: January 11, 2002

By:



RONALD C. FEDUS

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